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In re Shigenori Ohkawa et al.
Application for Patent Term Extension
under 35 U.S.C. § 156
Filed: September 7, 2005
For: U.S. Patent No. 6,034,239

DECISION DISMISSING
PETITION UNDER
37 CFR 1.59

This is a decision on the patent owner's August 24, 2006 petition titled PETITION TO EXPUNGE CERTAIN PROPRIETARY INFORMATION FROM APPLICATION FOR EXTENSION OF PATENT TERM OF UNITED STATES PATENT NO. 6,034,239 UNDER 37 C.F.R. § 1.59.

On page 2 of the petition, the patent owner authorizes the Office to charge fees associated with the petition to deposit account number 50-0799. The $200 fee set forth in 37 CFR 1.17(g) for a petition under 37 CFR 1.59 has been charged.

The petition is before the Office of Patent Legal Administration of the United States Patent and Trademark Office.

SUMMARY

The patent owner's petition under 37 CFR 1.59 is dismissed for failure to comply with 37 CFR 1.59(b), MPEP 2760, and MPEP 724.02. The patent owner may request reconsideration.

REVIEW OF FACTS

1. U.S. Patent No. 6,034,239 issued on March 7, 2000, based on application number 08/812,168 filed March 6, 1997.

2. On September 7, 2005, patent owner Takeda Pharmaceutical Company Ltd. filed an application with the U.S. Patent and Trademark Office (Office) for patent term extension (PTE) under 35 U.S.C. § 156.

3. Pursuant to 35 U.S.C. § 156(d)(2)(A)(ii), the Office forwarded a copy of the PTE application to the Food and Drug Administration (FDA) on October 11, 2005. The Office requested the FDA's assistance in determining that the identified

product, ROZEREM™ (ramelteon), had been subject to the required regulatory review period, and that the PTE application had been filed within the statutory time period.

4. On February 24, 2006 the FDA replied to the Office, stating that the product had been subject to a regulatory review as required by 35 U.S.C. § 156(a)(4), and that the review had authorized the first commercial marketing or use of the product under 35 U.S.C. § 156(f)(1). The FDA also verified that the PTE application had been timely filed.

5. On March 28, 2006, the Office informed the FDA that since the patent was considered to be eligible for patent term extension, it was necessary that the FDA determine the length of the applicable regulatory review period.

6. On June 19, 2006, the FDA published a Federal Register notice (71 Fed. Reg. 31275) regarding its determination of the regulatory review period. The period for requesting review of the FDA's determination expired on August 18, 2006. The period for petitioning for a determination of whether the applicant for PTE acted with due diligence before the FDA during regulatory review will expire on December 18, 2006.

7. The patent owner filed the instant petition to expunge pages 1-4 and 6-38 of Exhibit C (all pages except page 5) on August 24, 2006.

DECISION

Proceedings concerning PTE applications are public; see MPEP 2753. Under current practice, when a PTE application is filed with the Office it is made publicly available via the web site as part of the patent application file.

The instant petition requests that all pages of Exhibit C except page 5 be expunged. The petition was filed under 37 CFR 1.59, which states in pertinent part:

> (a) (1) Information in an application will not be expunged, except as provided in paragraph (b) of this section or § 41.7(a) of this title.
>
> . . .
>
> (b) An applicant may request that the Office expunge information, other than what is excluded by paragraph (a)(2) of this section, by filing a petition under this paragraph. Any petition to expunge information from an application must include the fee set forth in § 1.17(g) and establish to the satisfaction of the Director that the expungement of the information is appropriate in which case a notice granting the

petition for expungement will be provided.

MPEP 2760 is also relevant to the issue at hand, stating in pertinent part:

> There is no provision in the statute or the rules for withholding from the public any information that is submitted to the Office or the regulatory agency relating to an application for patent term extension. While one submitting such materials to the Office in relation to a pending application for patent term extension must generally assume that such materials will be made of record in the file and be made public, the Office is not unmindful of the difficulties this sometimes imposes. Proprietary or trade secret information should be submitted generally in accordance with the procedures set forth in MPEP § 724.02. Identification of the propriety or trade secret material should be made by page, line, and word, as necessary. The Office will not in the first instance undertake the task of determining the precise material in the application which is proprietary or trade secret information. Only the applicant is in a position to make this determination. See In re Schering-Plough Corp., 1 USPQ2d 1926, 1926 (Comm'r Pat. & Tm. 1986).

It should be noted that the present record does not reflect that the materials for which the patent owner now requests expungement were submitted in compliance with MPEP 724.02. That section of the MPEP 724.02 provides:

> Information which is considered by the party submitting the same to be either trade secret material or proprietary material, and any material subject to a protective order, must be clearly labelled as such and be filed in a sealed, clearly labelled, envelope or container. Each document or item must be clearly labelled as a "Trade Secret" document or item, a "Proprietary" document or item, or as an item or document "Subject To Protective Order." . . . Of course, the envelope or container, as well as each of the documents or items, must be labelled with complete identifying information for the file to which it is directed, including the Office or area to which the envelope or container is directed.
>
> . . .
>
> The envelope or container must be accompanied by a transmittal letter which also contains the same identifying information as the envelope or container. The transmittal letter must also state that the materials in the envelope or container are considered trade secrets or proprietary, or are subject to a protective order, and are being submitted for consideration under MPEP § 724.

Although the top of each page of Exhibit C is clearly marked "Confidential Document Takeda Property," those pages of Exhibit C that the patent owner now petitions to have

expunged from the record were not submitted in a sealed and labelled envelope or container as required. Instead, the patent owner submitted the entire PTE application packet including Exhibit C to the Office via U.S. mail directed to "Mail Stop: Patent Extension." The mailing was logged in at the Office of Initial Patent Examination on September 7, 2005, and received by the Office of Petitions on September 9, 2005. Therefore, in accordance with Office rules and procedures, any member of the public could have requested and been granted access to Exhibit C and the remaining PTE application documents beginning in September 2005. Furthermore, in accordance with current practice, the entire PTE application was posted on the Office web site in due course, and became publicly available over the Internet. The Office has no way of knowing whether the PTE application was actually accessed by any member of the public.

In addition, and as indicated above, a copy of the entire PTE application including Exhibit C was forwarded by the Office to the FDA on October 11, 2005. The patent owner is advised that the Office has no control over FDA practice regarding access to PTE application files. Thus it is possible that the material for which expungement is requested has already been publicly accessible via the FDA in addition to via the Office.

The first sentence on page 3 of the petition states, "Public release of this information would be irreparably detrimental to Takeda." No other explanation of harm to Takeda associated with release of the information is provided. The patent owner's statement as to irreparable detriment does not satisfy the obligation under 37 CFR 1.59(b) to "establish to the satisfaction of the Director that the expungement of the information is appropriate" because it is entirely conclusory. It does not explain how irreparable damage will occur if the Director now declines to expunge the information, in view of the fact that the information for which expungement is requested had been publicly released nearly a year before the instant petition was filed.

For the foregoing reasons, the petition under 37 CFR 1.59 is dismissed. The patent owner failed to comply with 37 CFR 1.59(b), MPEP 2760, and MPEP 724.02.

The patent owner may submit additional information and request reconsideration of this decision within **TWO MONTHS** of the date of this letter. This period for response is non-extendable. Note that per MPEP 2760, second paragraph, a suitable petition to expunge must be submitted prior to issuance of the certificate of extension. Barring any petition to establish due diligence during the regulatory process before the FDA, or any other unexpected delay, the FDA's determination of the regulatory review period will become final on December 18, 2006 and the certificate of extension will issue in due course thereafter. If no reply to this decision is received within two months of the date of this letter, this decision will become a final agency action within the meaning of 5 U.S.C. § 704.

CONCLUSION

1. The petition under 37 CFR 1.59 is dismissed.

2. The patent owner may request reconsideration of this decision within **TWO MONTHS** of the date of this letter.

3. This decision will become a final agency action within the meaning of 5 U.S.C. § 704 if no request for reconsideration is submitted within two months.

4. Telephone inquiries related to this decision should be directed to Kathleen Kahler Fonda, Legal Advisor, at (571) 272-7754.

Robert Spar
Director
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy